PPTA
Plasma Protein Therapeutics Association

August 10, 2004 **Via E-mail & USPS**
Reference No. **FDAA04017**

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Guidance for Industry, "Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Using Screening Human Donors of Blood and Blood Components Draft Guidance." Docket No. 2004D-0198.

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide comments on the Food and Drug Administration's (FDA) Draft Guidance entitled, "Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components Draft Guidance." [hereinafter "Draft Guidance"] In our letter to FDA Dockets Management of April 26, 2004, PPTA noted that we had not yet reviewed the Draft Guidance in detail; this current letter represents a more detailed response to the Draft Guidance and appends the comments of April 26, 2004.

PPTA is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies. Our members provide 60 percent of the world's needs for Source Plasma and protein therapies. These include clotting therapies for individuals with bleeding disorders, immunoglobulins to treat a complex of diseases in persons with immune deficiencies, therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits life expectancy, and albumin which is used in emergency room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these medically needed life-sustaining therapies.

Initially, PPTA poses a general comment on the overall tone of the Draft Guidance. PPTA recognizes that FDA cannot require implementation of the donor history questionnaire (DHQ) prepared by AABB's Interorganizational Task Force for the Donor History Questionnaire since elements of the DHQ surpass regulatory requirements for donor screening and acceptance. However, the value-neutral tone of the guidance does not impart FDA's "current thinking" on the desirability of standardization and uniformity in donor questioning. In its February 25, 1997 report entitled, "Blood Supply: FDA Oversight and Remaining Issues of Safety, PEMD-97-1," the U.S. General Accounting Office (GAO) noted the lack of standardization in donor screening as a weakness in the U.S. blood donation system. In light of the GAO Report and the intent of the Task Force's work in preparing a standardized DHQ, it would appear appropriate for FDA to impart a more positive tone with respect to implementing the DHQ. By doing so, the FDA moves closer toward addressing one of the weaknesses noted by the GAO.

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PPTA has a specific comment on question 24, which uses the term "lived with" as a risk factor for hepatitis. The glossary defines "lived with" as "residing in the same dwelling," with "examples: house, dormitory, apartment." PPTA views it more important to define the behaviors that denote risk rather than the types of dwelling, particularly with the example of "dormitory." Strict adherence to this definition might entail deferring donors living in today's modern dormitories that include few shared facilities.

PPTA encourages FDA to develop a strategy for flexible and timely guidance development to incorporate the abbreviated questionnaire developed by the Task Force and both the full-length and abbreviated questionnaires developed by PPTA's subgroup of the Task Force and changes to those questionnaires. At present, it appears that FDA plans to prepare individual guidance documents for each questionnaire. We encourage FDA to consider consolidating guidance documents into a single, comprehensive guidance that addresses donor history qualification issues. Changes in the questionnaires likely will be made in response to a new emerging infectious agent or other situation that requires addressing the overall donor qualification schema. It may be preferable to address those issues in the context of a comprehensive guidance document rather than individual, isolated documents.

Subsequent to our comment letter of April 26, 2004, we received the FDA Review Letter responding to the PPTA DHQ proposal and are currently studying the FDA commentary and suggestions contained in the review letter. We look forward to discussing these issues in the near future.

Please feel free to contact us with any questions you may have relating to the Draft Guidance.

Respectfully submitted,

Mary Gustafson
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Plasma Protein Therapeutics Association